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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,666	03/08/2006	Vincent Fischetti	600-1-295PCTUS	2384

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EXAMINER	
MARX, IRENE	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
10/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,666	FISCHETTI ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-14,18 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-17 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election with traverse of Group III, claims 15-17 and 19-23 on 7/21/08 is acknowledged. The traversal is on the ground(s) that the inventions are fundamentally related and that there would be no burden in examining more than one group.

However this is not found persuasive because the requirement of unity of invention is not fulfilled because there is no technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features "means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Compositions comprising at least two bacteriophage lytic enzymes in the treatment or prevention of bacterial infections are known in the art. See, e.g., U.S. Patent No. 6,056,954, col. 13, lines 16-25, and applicant has not shown otherwise.

In addition the question of burden of search is not an issue in restrictions in cases filed under 35 U.S.C § 371.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 15-17 and 19-23 are being considered on the merits. Claims 1-14, 18 and 24 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-17 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 19 are vague, indefinite and confusing in the recitation of "at least two therapeutically effective synergistic bacteriophage derived lytic enzymes" and "at least two bacteriophage derived synergistic lytic enzymes", respectively, since it is unclear whether the "lytic enzymes" are derived by chemical, physical or biological means. Amendment to -- obtained from-- would be remedial.

In addition, the phrase term "synergistic" renders claims 15 and 19 confusing, vague and indefinite, since there is no clear indication of the amount, identity, nature and source of the various bacteriophage derived enzymes intended to be "synergistic" and for what purpose. It is noted that an infinite number of enzymes is comprised by the invention in an unknown amount, and it is unlikely that synergism can be determined in this context.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-16, 19-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fischetti *et al.* (U.S. Patent No. 6,264,945) in light of Marova *et al.* (Folia Microbiol. 38 (3), 245- 252 (1993)).

The claims are directed to a composition comprising at least two therapeutically effective synergistic bacteriophage derived lytic enzymes and in particular an amidase, a muramidase, an endopeptidase, a glucosaminidase or combinations thereof.

Fischetti *et al.* teach a composition comprising at least two therapeutically effective lytic enzymes and in particular an amidase, a muramidase, an endopeptidase, a glucosaminidase or combinations thereof. See, e.g., col. 7, lines 9-25, wherein it is taught that a phage lysin is combined with lysostaphin. It is noted that lysostaphin comprises hexosaminidase (N-acetylglucosaminidase), glycylglycine-endopeptidase and N-acetylmuramyl-L-alanine-amidase, as demonstrated by Marova *et al.*.(See, e.g., page 245, paragraph 2).

Therefore, reference an enzyme composition appears to be identical to the presently claimed composition, since it comprises enzymes having the same activity as claimed. There is nothing on the record to suggest that any and all enzymes from bacteriophages differ in their properties from the enzymes disclosed by the reference. The referenced enzyme composition appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it has the same enzymatic activities and is taught to be effective for the same purpose. Consequently, the claimed enzyme composition appears to be anticipated by the reference.

In the alternative, even if the claimed enzyme composition is not identical to the referenced enzyme composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced enzyme composition is likely to inherently possess the same characteristics of the claimed enzyme particularly in view of the similar characteristics which they have been shown to share. Thus the claimed enzyme would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 15-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischetti *et al.* (I)(U.S. Patent No. 6,264,945) taken with Marova *et al.* (Folia Microbiol. 38 (3), 245- 252 (1993)), Fischetti *et al.* (II)(U.S. Patent No. 6,056,954), Sanz *et al.* (Eur. J. Biochem. 187,409-416 (1990)) and Loeffler *et al.* (Science **294:**2170-2172).

The claims are directed to a composition comprising at least two therapeutically effective synergistic bacteriophage derived lytic enzymes and in particular an amidase, a muramidase, an endopeptidase, a glucosaminidase or combinations thereof, in particular Cpt-1 and Pal.

Fischetti *et al.* (I) teach a composition comprising at least two therapeutically effective lytic enzymes and in particular an amidase, a muramidase, an endopeptidase, a glucosaminidase or combinations thereof. See, e.g., col. 7, lines 9-25, wherein it is taught that a phage lysin is combined with lysostaphin. It is noted that lysostaphin comprises hexosaminidase (N-acetylglucosaminidase), glycylglycine-endopeptidase and N-acetylmuramyl-L-alanine-amidase, as demonstrated by Marova *et al.* (See, e.g., page 245, paragraph 2).

The composition of Fischetti *et al.* differs from the claimed composition in that it is not specifically indicated as being "bacteriophage derived" and in comprising Pal and/or Cpl-1.

However, Fischetti *et al.* (II) strongly suggests the use of several bacteriophage lytic enzymes in combination. See, e.g., col. 13, lines 16-25.

In addition, Loeffler *et al.* teach the favorable properties of the cell wall degrading enzyme Pal, while Sanz *et al.* teach the favorable properties of Cpl-1 lysozyme. The references indicate both of which enzymes are active on the dangerous pathogen *P. pneumoniae*. See, e.g., respective Abstracts and Loeffler *et al.,* page 270, paragraph 1; Sanz *et al.,* page 410, paragraph 5.

One of ordinary skill in the art would have had a compelling motivation in providing a combination of various bacteriophage derived enzymes as taught by Fischetti *et al.* (II) and/or replacing the lysostaphin degradative enzymes in the composition of Fischetti *et al.* (I) with various bacteriophage derived enzymes having the same or similar degradative activity, such as Pal and Cpl-1 for their recognized beneficial properties that include specificity for certain dangerous pathogenic bacteria as well as stability.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition of Fischetti *et al.* (I) by replacing the degradative enzymes therein with bacteriophage derived degradative enzymes as taught by Fischetti *et al.* (II) or adding the specific bacteriophage degradative enzymes Pal and Cpl-1 as suggested by the teachings of Loeffler *et al.* and Sanz *et al.* for the expected benefit of providing an enzyme composition that is known to have powerful degradative activity and suitable for the control of dangerous and resistant bacterial pathogens such as *P. pneumoniae.*

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651